K122532

510(k) Summary
[As Required by 21 CFR 807.92(c)]

510(k) Owner: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Official Contact: Melissa S. Gonzalez
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Date Summary Prepared: February 21, 2013

Trade Name: *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories

Common Name: *Endoscope and accessories*

Product Code: NAY, GCJ

Classification: *Endoscope and Accessories, 21 CFR 876.1500*

Predicate Devices:

- *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories (K112208/K120215)
- SILS™ Clincher, SILS™ Dissector, SILS™ Grasper, SILS™ L-Hook, SILS™ Shears (K091869)
- *Intuitive Surgical® da Vinci®* Surgical System and Endoscopic Instruments (K081137/K050404)

Device Description:
The *da Vinci Single-Site* Instruments and Accessories consist of semi-rigid shaft instruments, two fixed-shape curved cannulae (250 mm and 300 mm length), an accessory cannula for insertion of manual laparoscopic instruments, a semi-rigid blunt obturator (250 mm and 300 mm length), and a *Single-Site* Port (with insufflation tubing and stopcock) for the placement and insertion of multiple cannulae/instruments through a single incision.

The *da Vinci Single-Site* Instruments and Accessories include instruments to perform grasping, cautery, cutting, clip ligation, suturing, and suction/irrigation functions. The instruments are non-wristed (similar to the predicate laparoscopic instruments). The *da Vinci Single-Site* Instruments and Accessories are intended to be used with the existing IS3000 *da Vinci Si* Surgical System.

Intended Use:
The *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories used with the *da Vinci® Si* Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single-incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the 5 mm *Single-Site* Port.

Technological Characteristics:
The *Intuitive Surgical da Vinci Single-Site* Instruments and Accessories are identical to the predicate *Single-Site* devices in terms of their technological characteristics. The only change to the cleared *da Vinci Single-Site* Instruments and Accessories is the addition of two instruments (*Single-Site* Needle Driver and *Single-Site* Bipolar Maryland), both of which are substantially equivalent to previously cleared versions of these instruments used with the *da Vinci* Multi-Port System. The proposed indications for use are a subset of the indications cleared for the Covidien predicate device.

Performance Data:
Bench, animal, and cadaver testing demonstrate that the subject device is substantially equivalent to the predicate devices and that the design output meets the design input requirements. The differences do not raise any new issues of safety or effectiveness as compared to the predicate devices. In addition, an acute animal study was performed to validate the quality and effectiveness of closure of suture lines with the *Single-Site* Needle Driver and to establish substantial equivalence between the curved needle driver and the SILS Port and manual single incision instruments.

Summary:
Based on the intended use, indications for use, technological characteristics and performance data, the *Intuitive Surgical da Vinci Single-Site* Instruments and Accessories are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center– WO66-G609
Silver Spring, MD 20993-0002

Intuitive Surgical, Incorporated
% Ms. Melissa S. Gonzalez
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086-5206

Letter dated: March 5, 2013

Re: K122532
Trade/Device Name: da Vinci® Single-Site™ Instruments and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: December 28, 2012
Received: January 02, 2013

Dear Ms. Gonzalez:

This letter corrects our substantially equivalent letter of February 19, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if known: K122532

Device Name: *da Vinci® Single-Site™* Instruments and Accessories

INDICATIONS FOR USE:

The *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories used with the *da Vinci® Si* Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single-incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the 5 mm *Single-Site* Port.

Prescription Use __X__ AND/OR Over-the-Counter Use _____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003699256
Date: 2013.03.04 08:09:36 -05'00'

_____ for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number __k122532_____